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**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA**

THE PERSONAL CARE PRODUCTS
COUNCIL,

Plaintiff,

v.

ROB BONTA, in his official capacity as
Attorney General of the State of California,

Defendant.

Case No. 2:23-CV-01006-TLN-JDP

**PLAINTIFF PERSONAL CARE
PRODUCTS COUNCIL'S
MEMORANDUM OF POINTS AND
AUTHORITIES IN SUPPORT OF
MOTION FOR SUMMARY
JUDGMENT**

Judge: Hon. Troy L. Nunley
Hearing: November 14, 2024
Time/Room: 2:00 p.m. in Courtroom 2
Action Filed: May 26, 2023

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INTRODUCTION

1
2 Consistent with two decisions of this Court that were upheld by the Ninth Circuit rejecting
3 Proposition 65 cancer warnings for other listed chemicals,¹ this Court recently issued a preliminary
4 injunction against enforcement of the Proposition 65 warning requirement for titanium dioxide
5 (airborne, unbound particles of respirable size) (“Listed Titanium Dioxide”) in cosmetics and
6 personal care products. ECF No. 40. On virtually the same record, following discovery confirming
7 the facts in all material respects, Plaintiff Personal Care Products Council (“PCPC”) now seeks
8 summary judgment, including a permanent injunction and declaration, to resolve this lawsuit.

9 The material facts are undisputed. The State of California has not determined that Listed
10 Titanium Dioxide causes cancer in humans. Indeed, no regulatory agency or scientific body has
11 done so. The foreign entity whose decision triggered the listing of this substance under Proposition
12 65—the International Agency for Research on Cancer (“IARC”)—itself found “inadequate
13 evidence” that Listed Titanium Dioxide causes cancer in humans (i.e., no causal association). It
14 classified the substance as “possibly carcinogenic to humans”—and therefore possibly *not*
15 carcinogenic to humans—based on two rat studies that reputable scientists find irrelevant to
16 humans. Meanwhile, the U.S. Food & Drug Administration has continuously approved titanium
17 dioxide as a color additive that can safely be used in cosmetics, foods, and drugs, and as an active
18 ingredient that is safe and effective in sunscreen products.

19 Nevertheless, Proposition 65 compels sellers of cosmetics and personal care products
20 containing Listed Titanium Dioxide to warn consumers that the product can expose them to a
21 chemical “known to the State of California to cause cancer”—that is, unless they are willing to
22 endure the risk and expense of litigation by private enforcers with monetary incentives to prove
23 that the level of exposure to average consumers from use of their product poses “no significant
24 risk” using technical and debatable standards. Because this warning is misleading, controversial,
25 unjustified, and unduly burdensome, it violates the First Amendment and should be struck down.

26
27 ¹ *Cal. Chamber of Com. v. CERT*, 29 F.4th 468 (9th Cir. 2022) (“*CERT*”), *aff’g Cal. Chamber of Com. v. Becerra*, 529 F. Supp. 3d 1099, 1103 (E.D. Cal. 2021) (“*CalChamber*”) (acrylamide); *Nat’l Ass’n of Wheat Growers v. Bonta*, 85 F.4th 1263 (9th Cir. 2023) (“*NAWG*”), *aff’g Nat’l Ass’n of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247 (E.D. Cal. 2020) (“*Wheat Growers II*”) (glyphosate).

BACKGROUND AND UNDISPUTED FACTS

Titanium Dioxide and its Classification by IARC

Titanium dioxide is a mineral that is widely used as an ingredient in cosmetic and personal care products, including makeup (e.g., eyeshadow), sunscreens, and toothpastes. UMF No. 1. Worldwide, titanium dioxide has been used in these products since the 1930s. UMF No. 2. The FDA has concluded that titanium dioxide may be safely used as a color additive in a wide variety of products, including cosmetics, food and supplements, drugs, and sunscreens. UMF No. 3.

In 2010, IARC determined that titanium dioxide is “possibly carcinogenic to humans” due to “sufficient evidence” of carcinogenicity in experimental animals. UMF No. 4. IARC is not a regulator; its sole directive is to assess hazards. From these assessments, IARC “identifie[s] cancer hazards but does not evaluate the risks associated with specific levels or circumstances of exposure.”² UMF No. 7. IARC classifies an agent into one of four groups³ based on the strength of evidence that an exposure is carcinogenic. UMF No. 11. When IARC classified titanium dioxide as a Group 2B agent, it expressly stated that there is “inadequate evidence” of carcinogenicity in humans. UMF No. 4. More recent assessments of the epidemiological data are in accord.⁴ But because of two studies in rats that are decades old, titanium dioxide satisfied IARC’s criteria for being classified as a “possible human carcinogen.” UMF No. 14.

Supplying the basis for IARC’s classification, the Lee (1985) and Heinrich (1995) studies exposed rats to chronic lung overload conditions that overwhelmed their pulmonary physiology and caused them to develop lung tumors. UMF No. 20-21. Since their publication, both studies have been discredited and shown to have little to no relevance to humans. UMF No. 22. The

² A substance is considered a cancer *hazard* if it is capable of causing cancer at some theoretical level, whereas a *risk* measures the probability that cancer will occur considering the level of exposure. IARC identifies cancer hazards even when risks are very low with known patterns of exposure. UMF Nos. 8-10.

³ Group 1 (“carcinogenic to humans”) applies when there is “sufficient evidence” in humans. Group 2A (“probably carcinogenic”) chemicals have “limited evidence” in humans or “sufficient evidence of carcinogenicity” in animals. Group 2B (“possibly carcinogenic”) chemicals can have “limited evidence” in humans or “inadequate evidence” in humans but “sufficient evidence” in animals. Group 3 applies when the chemical is “not classifiable as to its carcinogenicity to humans.” UMF Nos. 12-15.

⁴ Dr. Boffetta, one of PCPC’s experts who is an “authoritative expert in epidemiology,” Jameson Dep. 70:3, concludes that “the weight of the existing literature shows that exposure to TiO₂ in any form does not cause cancer in humans.” Boffetta Report ¶ 56. *See also* Madl Report ¶¶ 43-54.

1 reasons for this include:

- 2 • The rats were exposed to excessive doses of titanium dioxide—for 6 hours (Lee)
3 or 18 hours (Heinrich) per day, 5 days per week for 2 years—well beyond
4 overload thresholds for retained particulate mass in the lungs; UMF No. 23.
- 5 • The mechanism by which titanium dioxide causes cancer in rats is lung overload,
6 which is a condition that humans have not been shown to experience from
7 exposure to titanium dioxide; UMF Nos. 25-26.
- 8 • Particle clearance and translocation pathways vary significantly between rodents
9 and non-rodent species like humans due to anatomical and physiological
10 differences (*e.g.*, size and number of pulmonary macrophages); UMF No. 27.
- 11 • The adverse outcome pathways (AOP) for particle overload leading to
12 tumorigenic responses is exclusive to rats; UMF No. 29.

13 Government authorities in Europe have cast further doubt on these studies. In 2017, for instance,
14 the European Chemicals Agency determined that the “excessive exposure [conditions] invalidates
15 the results of the Lee et al. (1985) study.” UMF No. 31. And in 2022, the European Court of
16 Justice annulled an earlier warning regulation of titanium dioxide after concluding that reliance on
17 the Heinrich (1995) study was “manifest error.” UMF No. 32.

18 *Proposition 65 and Titanium Dioxide’s Listing*

19 In 2011, based solely on IARC’s classification, California’s Office of Environmental Health
20 Hazard Assessment (“OEHHA”) added titanium dioxide (airborne, unbound particles of respirable
21 size) (“Listed Titanium Dioxide”) to the Proposition 65 list of chemicals that are known to the State
22 to cause cancer. UMF No. 33. OEHHA made no determination that Listed Titanium Dioxide or
23 any other form of titanium dioxide causes cancer in humans, and it has not done so in the
24 intervening 13 years. UMF No. 34.

25 Businesses whose products contain a substance on Proposition 65’s list must provide
26 Californians a “clear and reasonable warning” before “expos[ing] any individual” to the substance.
27 Cal. Health & Safety Code § 25249.6. OEHHA’s regulations deem cancer warnings for consumer
28 products containing Listed Titanium Dioxide, including the cosmetic and personal care products at
issue here, to be “clear and reasonable” if they state:

⚠WARNING: This product can expose you to chemicals including titanium
dioxide (airborne, unbound particles of respirable size), which is known to the
State of California to cause cancer. For more information, go to
www.P65Warnings.ca.gov.

1 27 Cal. Code Regs. § 25603(a)(2)(A). Alternatively, the warning can be provided in a short form:



2 **WARNING:** Cancer – www.P65Warnings.ca.gov.

3 27 Cal. Code Regs. § 25603(b)(2)(A). These are known as “safe harbor warnings” because they
4 are approved by the State as compliant with Proposition 65 and protect businesses from liability if
5 they use these warnings. Although other forms of warnings are technically permitted, “only the
6 safe harbor warning is actually useable in practice.” *CalChamber*, 29 F.4th at 479.

7 Proposition 65 provides an affirmative defense to this warning requirement if a business
8 “can show that the exposure poses no significant risk assuming lifetime exposure at the level in
9 question.” Cal. Health & Safety Code § 25249.10(c). This threshold is referred to as the “No
10 Significant Risk Level,” or “NSRL.” For some listed substances, OEHHA has published a “safe
11 harbor” NSRL, a presumptive, daily exposure-based limit below which a business is not obligated
12 to warn. Cal. Code Regs. tit. 27, § 25705. For Listed Titanium Dioxide and other chemicals,
13 however, OEHHA has not designated a “safe harbor” NSRL.⁵ In those circumstances, a defendant
14 must establish the appropriate NSRL in litigation and prove that its product exposes average
15 consumers to a level of the chemical below that level. *Id.* §§ 25703 *et seq.*

16 The Attorney General, district attorneys, and certain city attorneys may bring an
17 enforcement action under Health & Safety Code § 25249.7(c). Proposition 65 imposes penalties
18 of up to \$2,500 *per day* for *each* failure to provide an adequate warning. *Id.* § 25249.7(b). It also
19 authorizes courts to enjoin any person who “threatens to violate” the warning requirement. *Id.*
20 § 25249.7(c). Notably, the statute also permits private citizens (or organizations) to bring
21 enforcement actions as well. *Id.* § 25249.7(d). Private enforcers recover a “bounty” of 25 percent
22 of the civil penalty (*id.* § 25249.12(d)), as well as their attorneys’ fees (Cal. Code Civ. Proc. §
23 1021.5), creating very strong incentives for private enforcement.⁶

24 _____
25 ⁵ On May 10, 2024, OEHHA proposed a regulation to adopt an NSRL for Listed Titanium Dioxide. The
26 public comment period ended on July 1, 2024, and the proposed regulation remains pending.

27 ⁶ Courts have long recognized how onerous and ripe for abuse these private enforcement suits under
28 Proposition 65 can be on businesses. *See, e.g., B&G Foods N. Am., Inc. v. Embry*, 29 F.4th 527, 533 (9th
Cir. 2022) (observing that “businesses often choose to settle Prop. 65 cases” because establishing a safe
harbor defense is “very burdensome”); *Consumer Def. Grp. v. Rental Hous. Indus. Members*, 137 Cal. App.
4th 1185, 1214 (2006) (describing how provisions make it “virtually impossible” for defendants “to defend
a warning action on the theory that the amount of carcinogenic exposure is so low as to pose ‘no significant

1 Procedural History and Relevant Litigation

2 PCPC filed this case in May 2023, bringing an as-applied challenge to Proposition 65's
3 warning requirement under the First Amendment against the California Attorney General ("AG"),
4 and seeking declaratory and injunctive relief. Compl., ECF No. 1. PCPC moved for a preliminary
5 injunction in October 2023 against the AG and all those in privity with him from filing or
6 prosecuting new lawsuits to enforce the Proposition 65 warning requirement as applied to Listed
7 Titanium Dioxide in cosmetic and personal care products. ECF No. 27.

8 The Court granted PCPC's motion for a preliminary injunction in June 2024, finding that
9 PCPC was likely to succeed on the merits of its First Amendment claim. ECF No. 40. Applying
10 *Zauderer's* test for government-compelled speech, the Court correctly held that the warning
11 requirements for Listed Titanium Dioxide are "not purely factual because they tend to mislead the
12 average consumer." *Id.* at 16. The Court observed that "the organization that prompted Listed
13 Titanium Dioxide's inclusion on the Prop 65 list—IARC—specifically found that there is
14 *inadequate evidence* for the carcinogenicity of titanium dioxide *in humans.*" *Id.* (emphasis added).
15 For that reason, the Court rightly concluded that average consumers are misled by the compelled
16 warning, which reasonably understood conveys that Listed Titanium Dioxide causes cancer in
17 humans or will increase their risk of cancer. *Id.* at 15-16.

18 That conclusion marks the third occasion this Court has ruled in as-applied challenges that
19 Proposition 65 fails or is likely to fail the constitutional standard under *Zauderer*. The first
20 addressed the warning requirement for glyphosate, a pesticide that IARC classified as a Group 2A
21 substance ("probably carcinogenic to humans") after determining that there is "*limited evidence* of
22 carcinogenicity in humans" but sufficient evidence in animals. UMF No. 35. After preliminarily
23 enjoining the enforcement of Proposition 65 as to glyphosate, *see Nat'l Ass'n of Wheat Growers v.*
24 *Zeise*, 309 F. Supp. 3d 842 (E.D. Cal. 2018) ("*Wheat Growers I*"), Judge Shubb ultimately ruled
25 that the warning requirement failed First Amendment scrutiny and granted summary judgment
26 against the State. *Wheat Growers II*, 468 F. Supp. 3d at 1265. That decision was affirmed last

27 _____
28 risk' short of an actual trial"); *Consumer Cause, Inc. v. SmileCare*, 91 Cal. App. 4th 454, 477 (2001) (Vogel,
J., dissenting) (describing Proposition 65 lawsuits as "judicial extortion").

1 November. *NAWG*, 85 F.4th at 1266 (upholding permanent injunction and declaring Proposition
2 65’s warning requirement as applied to glyphosate unconstitutional).

3 In the second challenge, this Court preliminarily enjoined enforcement of Proposition 65 as
4 to acrylamide in food, a chemical that IARC also classified as a Group 2A substance with
5 “sufficient evidence [of carcinogenicity] in experimental animals” but “*inadequate evidence*” in
6 humans. UMF No. 36. Chief Judge Mueller’s ruling was affirmed by the Ninth Circuit, which
7 held that enforcement of the warning requirement as to acrylamide in food was “likely
8 unconstitutional.” *CERT*, 29 F.4th at 482-83.

9 Since titanium dioxide was listed under Proposition 65, six private enforcers have issued
10 572 notices of violation and have pursued enforcement actions against manufacturers and retailers
11 of cosmetics and personal care products, securing hundreds of thousands of dollars in settlement
12 payments. UMF No. 58. The most recent round of notices began in July 2021 and continues today.
13 It includes 561 notices of violation to manufacturers and retailers of color cosmetics and has
14 resulted in settlement agreements with more than 50 companies for over \$2,000,000 in civil
15 penalties and nearly \$2,000,000 in attorney’s fees and costs. UMF No. 59. These notices have to
16 date resulted in 124 lawsuits by private enforcers, most of which are now consolidated before the
17 San Francisco Superior Court. UMF No. 60. Notices of violation of Proposition 65 as to Listed
18 Titanium Dioxide continue to be served on cosmetic companies, with the most recent one issued
19 on August 29, 2024. UMF No. 61.

20 **STANDARD**

21 The Court “shall grant summary judgment if the movant shows that there is no genuine
22 dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R.
23 Civ. P. 56(a). Thus, “[s]ummary judgment is appropriate when, viewing the evidence in the light
24 most favorable to the nonmoving party, there is no genuine dispute as to any material fact.” *Italian*
25 *Colors Rest. v. Becerra*, 878 F.3d 1165, 1171 (9th Cir. 2018) (citation omitted). Further, because
26 this action challenges a government-compelled disclosure, the government “has the burden” to
27 establish that its law passes First Amendment scrutiny. *Am. Beverage Ass’n v. City & Cty. of S.F.*,
28 916 F.3d 749, 756 (9th Cir. 2019) (en banc) (“*ABA*”).

ARGUMENT

1
2 The undisputed record establishes that Proposition 65’s warning requirement for Listed
3 Titanium Dioxide in cosmetic products violates the First Amendment. Because the AG has not
4 carried his burden, summary judgment should be entered in favor of PCPC, along with a declaration
5 and a permanent injunction against enforcement of the warning requirement for Listed Titanium
6 Dioxide in cosmetics and personal care products.

7 **I. THE COMPELLED CANCER WARNING IS UNCONSTITUTIONAL.**

8 Regulations of commercial speech are generally subject to intermediate scrutiny—that is,
9 the State must show that the regulation “directly advances” a “substantial” government interest and
10 is “not more extensive than is necessary to serve that interest.” *Central Hudson Gas & Elec. Corp.*
11 *v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980). There is a narrow exception to this rule under
12 which courts “appl[y] a lower level of scrutiny to laws that compel disclosures,” but only “in certain
13 contexts.” *Nat’l Inst. of Family & Life Advocs. v. Becerra*, 585 U.S. 755, 768 (2018) (“*NIFLA*”
14 (citing *Zauderer v. Off. of Disc. Counsel*, 471 U.S. 626, 651 (1985))). Under that standard,
15 government-compelled speech is permissible only if it is “(1) purely factual, (2) noncontroversial,
16 and (3) not unjustified or unduly burdensome.” *ABA*, 916 F.3d at 756. Compelled disclosures
17 “must meet all three criteria to be constitutional.” *Id.*

18 There is no presumption that State-mandated disclosures meet this standard. Instead, “[t]he
19 State has the burden of demonstrating that” each element is satisfied. *Wheat Growers II*, 468 F.
20 Supp. 3d at 1258. The AG cannot meet his burden to make any of these showings here, let alone
21 all three. And because “the warning does not meet [this] lower standard [under *Zauderer*], it
22 necessarily does not meet [the] higher standard” under *Central Hudson*. *ABA*, 916 F.3d at 756 n.5.
23 The Proposition 65 warning requirement for Listed Titanium Dioxide in cosmetics and personal
24 care products therefore is unconstitutional.

25 **A. The Warning Is Not “Purely Factual and Uncontroversial.”**

26 “When the government takes the momentous step of mandating that its message be
27 delivered by private parties, it is exceptionally important that the compelled speech be purely
28 factual.” *ABA*, 916 F.3d at 767 (Christen, J., concurring). Courts applying *Zauderer*, therefore,

1 only uphold compelled disclosures of purely factual information, the accuracy of which cannot be
 2 reasonably disputed. *See, e.g., Am. Meat Inst. v. Dep’t of Agric.*, 760 F.3d 18, 27 (D.C. Cir. 2014)
 3 (product’s country of origin); *New York State Rest. Ass’n v. New York City Bd. of Health*, 556 F.3d
 4 114, 134 (2d Cir. 2009) (calorie counts on food menus).

5 A “factually accurate” disclosure, however, “is not enough to qualify for the *Zauderer*
 6 exception.” *NAWG*, 85 F.4th at 1276. “[A] statement may be literally true but nonetheless
 7 misleading and, in that sense, untrue.” *CTIA-The Wireless Ass’n v. City of Berkeley*, 928 F.3d 832,
 8 847 (9th Cir. 2019) (“*CTIA II*”). In determining whether a public health warning is misleading,
 9 courts must consider how that speech will be understood “not just [by] those with sophisticated
 10 levels of health literacy,” but by “unsophisticated consumers” too. *ABA*, 916 F.3d at 766 (Christen,
 11 J., concurring); *cf. Wheat Growers I*, 309 F. Supp. 3d at 851 (“Ordinary consumers do not interpret
 12 warnings in accordance with a complex web of statutes, regulations, and court decisions. . .”).

13 Further, as the Ninth Circuit has held on two occasions, a Proposition 65 cancer warning is
 14 not “uncontroversial”—and therefore ineligible for review under the *Zauderer* standard—where
 15 there is “robust disagreement by reputable scientific sources” over the human carcinogenicity of
 16 the chemical. *NAWG*, 85 F.4th at 1277 (citing *CERT*, 29 F.4th at 478).⁷

17 Here, because the cancer warning requirement for Listed Titanium Dioxide compels
 18 businesses to disparage their products with a highly misleading and fiercely debated message, the
 19 AG cannot show that it meets the more relaxed standard under *Zauderer*, and the warning
 20 requirement as applied here must be held unconstitutional.

21
 22 1. Proposition 65 Requires a Message That Products Containing Listed Titanium
 Dioxide Will Increase Consumers’ Risk of Cancer.

23 As this Court correctly observed, “Prop 65 is principally concerned about chemicals that
 24 are carcinogenic to *humans*, not animals.” ECF No. 40 at 15. Furthermore, “[a]t its core, the
 25

26 ⁷ Notably, in both *NAWG* and *CERT*, the Ninth Circuit considered chemicals that IARC classifies as
 27 “*probably* carcinogenic to humans” (Group 2A), whereas titanium dioxide is only classified as “*possibly*
 28 carcinogenic” (Group 2B). The strength of evidence behind Group 2B chemicals is necessarily *weaker* than
 that of Group 2A. UMF Nos. 13-18, 35-36. IARC’s Group 2A classification of glyphosate, moreover, was
 based on its determination that the epidemiological evidence showed “limited evidence of carcinogenicity”
 in humans (i.e., a causal relationship was credible but could not be established).

1 function of Prop 65 is to inform consumers of *risks*, not *hazards*.” *NAWG*, 85 F.4th at 1269
2 (emphasis added); *cf.* Cal. Code Regs. tit. 27, § 25701 (explaining that a certain chemical need not
3 include the statutory warning if it “pose[s] no significant risk”). The ballot argument that swayed
4 California voters to adopt the law assured them that Proposition 65’s focus would be on “chemicals
5 that are scientifically known—not merely suspected, but known—to cause cancer and birth
6 defects.” *People ex rel. Lungren v. Sup. Ct.*, 14 Cal. 4th 294, 307 (1996) (quoting Proposition 65
7 ballot pamphlet); *cf. Nicole-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 661 (1991) (noting its
8 “statutory purpose” includes “removing from regulatory scrutiny those substances which pose only
9 an ‘insignificant risk’ of cancer”). Even the AG concedes that “Californians passed the law out of
10 concern that hazardous chemicals pose a serious potential threat to their health and well-being.”
11 ECF No. 30 at 8 (citation and internal quotations omitted).

12 In line with that intent, the statute’s “clear and reasonable” warning requirement applied
13 here compels businesses to convey to consumers that their product “can expose [them] to chemicals
14 including [Listed Titanium Dioxide], which is known to the State of California to cause cancer,”
15 or “words to that effect.” *See Dowhal v. SmithKline Beecham Cons. Healthcare*, 32 Cal. 4th 910,
16 918 (2004). The AG’s own regulations also expressly preclude “use of the adverb ‘may’ to modify
17 whether the chemical causes cancer,” as well as any other language that “obfuscates” the core
18 warning. *See* Cal. Code Regs. tit. 11, § 3202(b). Thus, the plain meaning of any warning for Listed
19 Titanium Dioxide—whether a short-form, long-form, or other substantially similar warning—must
20 convey that the product will increase consumers’ risk of getting cancer.

21 But even more than what it *must* convey, the warning is also reasonably understood to carry
22 that meaning. Without relying on the consumer survey PCPC commissioned, in issuing its
23 preliminary injunction this Court agreed with PCPC and found it “reasonable for the average
24 consumer” to conclude from reading the required warning that Listed Titanium Dioxide causes
25 cancer in humans or will increase a consumer’s risk of cancer. ECF No. 40 at 15-16. In the words
26 of Judge Shubb, who also found it unnecessary to rely on any consumer survey data, “the most
27 obvious reading of the Proposition 65 cancer warning is that exposure to [the named chemical] in
28 fact causes cancer.” *See Wheat Growers I*, 309 F. Supp. 3d at 851.

1 2. PCPC’s Consumer Survey Confirms this Court’s Plain Reading of the Warning.

2 But if there is any doubt, PCPC’s consumer survey illustrates that, when presented with a
3 cosmetic product bearing a cancer warning for Listed Titanium Dioxide, the overwhelming
4 majority of consumers—approximately three quarters—do in fact take away the (mistaken) belief
5 that the product will cause them to get cancer or increase their risk of cancer. UMF No. 37.⁸ Indeed,
6 in another as-applied challenge to the Proposition 65 warning requirement, this Court accepted the
7 results from a similar consumer survey that Dr. Nowlis also designed and conducted, which had
8 similar results with a similar warning for a different chemical. UMF No. 38-39.⁹

9 Hoping to rebut the survey’s empirical findings, the AG retained a professor of
10 environmental studies to critique the survey’s design¹⁰ and audit whether the Nowlis Report’s
11 conclusions are supported by the survey data. UMF No. 40. The AG’s expert, Dr. Joseph Arvai,
12 has never conducted or designed a survey for use in litigation. UMF No. 41. He has never
13 published an evaluation of another expert’s survey. UMF No. 42. Nor has he published a study
14 evaluating consumer product warnings. UMF No. 43. And like the state agency that originated the
15 safe harbor warnings in the first place, Dr. Arvai did not conduct a survey to assess how consumers
16 perceive the Proposition 65 warning at issue here. UMF No. 44.

17 Nevertheless, the AG’s expert still re-crunched the numbers according to his own
18 methodology. UMF No. 45. He evaluated the responses of survey participants and categorized them
19 so as to distinguish among those who understand the warning to convey that using the eyeshadow
20 *can* or *might* increase their risk of cancer as opposed to *will* increase their risk of cancer (or *will*

21 _____
22 ⁸ Dr. Nowlis found that a net 77.8 percent of eyeshadow purchasers reading the long-form warning—and
23 73.1 percent of those reading the short-form warning—interpret the warning on an eyeshadow package to
24 convey the message that using the product increases their risk of getting cancer. His opinion is that these
25 results are generalizable to other cosmetic products bearing the same warning. *See* Nowlis Report ¶¶ 9-10.

26 ⁹ Chief Judge Mueller cited that survey in reaching her conclusion that the Proposition 65 warning
27 requirement as applied to acrylamide in food was misleading. UMF No. 39. That decision was affirmed by
28 the Ninth Circuit, which also cited Dr. Nowlis’s survey in concluding that the challenged warning was likely
unconstitutional. *Id.*

¹⁰ In his unsuccessful opposition to PCPC’s Motion for a Preliminary Injunction (ECF No. 30), the AG cited
a handful of purported design flaws that Dr. Arvai raised in his rebuttal report. These criticisms are
addressed in PCPC’s Response to the AG’s Objections (ECF No. 32-2). But if the AG were to rehash these
objections, they should not lead to Nowlis’s Report being excluded. “Technical inadequacies” in a consumer
survey, “including the format of the questions or the manner in which it was taken, bear on the weight of the
evidence, not its admissibility.” *Keith v. Volpe*, 858 F.2d 467, 480 (9th Cir. 1988).

1 cause them to get cancer). UMF Nos. 46-49. Without any basis or citation, he thinks “these are
2 important distinctions.” UMF No. 49. In his view, a consumer who understands the warning to
3 mean the eyeshadow only might (or might not) increase their risk of cancer is not misled.¹¹

4 The problem for the AG is that even if the Court were to credit Dr. Arvai’s narrow parsing
5 and unsubstantiated presumptions about consumers’ understanding of cancer risks, the percentage
6 of respondents who are misled by either safe harbor warning is still more than sufficient for this
7 Court to conclude that the compelled warnings are not “purely factual.” Applying Dr. Arvai’s
8 methodology, Dr. Nowlis assessed the net percentages of respondents whose open-ended responses
9 indicated that using the eyeshadow product will cause cancer or lead to an increased risk of cancer.
10 UMF No. 50. Of the respondents presented with the short-form warning, 25.5% believe that using
11 the eyeshadow product increases their risk of getting cancer. UMF No. 51. Of those who were
12 presented with the long-form warning, that number grew to nearly 28%. UMF No. 52.

13 In the false advertising and trademark infringement contexts, there is no question that
14 liability attaches if a quarter of consumers are confused or misled. *See, e.g., P & P Imports LLC v.*
15 *Johnson Enters., LLC*, 46 F.4th 953, 962 n.3 (9th Cir. 2022) (observing that, in a test-control
16 designed consumer survey, a net confusion rate of 11% is sufficient to establish actual confusion
17 at the summary judgment stage); *CytoSport, Inc. v. Vital Pharm., Inc.*, 617 F. Supp. 2d 1051, 1076
18 (E.D. Cal. 2009) (collecting cases that found a likelihood of confusion was supported by a net
19 confusion rate of 15%). Indeed, courts nationwide have held that confusion rates of 15 percent or
20 higher can support a Lanham Act claim.¹²

21 “When the possibility of deception is as self-evident as it is in this case,” this Court “need
22

23 ¹¹ Of course, while a “might or might not” warning would be more accurate given the doubts over titanium
24 dioxide’s carcinogenicity in humans, it would certainly not “directly advance” a “substantial government
25 interest” as required by *Central Hudson*. *See infra* Part II.C. Nearly every chemical *might* or *might not*
26 increase a consumer’s risk of cancer; such warnings would be everywhere, reducing the effectiveness of
27 warnings for truly known risks. Such “might or might not” warnings would also be contrary to Proposition
28 65’s stated purpose: to warn consumers about exposures to “chemicals that are scientifically known—not
merely suspected, but known—to cause cancer” in humans. *Lungren*, 14 Cal. 4th at 306-07.

¹² *See, e.g., Church & Dwight Co. v. SPD Swiss Precisions Diagnostics*, 843 F.3d 48, 68-70 (2d Cir. 2016)
(affirming trial court’s finding that 16 to 17.3% was sufficient evidence of consumer confusion); *Rosetta
Stone Ltd. v. Google*, 676 F.3d 144, 159 (4th Cir. 2012) (holding that a confusion rate of 17% is “clear
evidence of actual confusion for purposes of summary judgment”); *Sally Beauty Co. v. Beautyco, Inc.*, 304
F.3d 964, 979-80 (10th Cir. 2002) (holding that 26% is “strong evidence of actual confusion”).

1 not require [Plaintiff] to conduct a survey of the public before it may determine that the [warning]
2 ha[s] a tendency to mislead.” *Zauderer*, 471 U.S. at 652-53 (internal quotations and original
3 alterations omitted). Although this Court has not relied on survey data in striking down Proposition
4 65’s warning requirement for glyphosate, *Wheat Growers II*, 468 F. Supp. 3d at 1266, or in
5 preliminarily enjoining the same requirement as to Listed Titanium Dioxide (ECF No. 40 at 15
6 n.6), PCPC’s consumer survey data reinforces the commonsense reading of the warning language.

7 In short, whichever evaluative method this Court uses—Proposition 65’s statutory purpose,
8 PCPC’s consumer survey evidence (even viewed through the AG’s rebuttal expert’s methodology),
9 or a plain reading—a cancer warning on cosmetic and personal care products leads consumers to
10 conclude that using the product will increase their risk of cancer. And the AG has presented no
11 affirmative evidence that consumers understand the warning to mean anything else.

12 3. The Proposition 65 Message is Unsupported by the Evidence.

13 As this Court correctly decided on the preliminary injunction motion, “such a conclusion is
14 misleading” as to Listed Titanium Dioxide (ECF No. 40 at 16), in part because IARC only classified
15 titanium dioxide as a “possible human carcinogen.” UMF No. 14; *see also CTIA-The Wireless*
16 *Ass’n v. City & Cnty. of S.F.*, 827 F. Supp. 2d 1054, 1060 (N.D. Cal. 2011), *aff’d* 494 F. App’x 752
17 (9th Cir. 2012) (noting that “[t]he uninitiated will tend to misunderstand” a cancer warning for a
18 Group 2B ‘possible carcinogen’” “as more dangerous than it really is”).

19 It is undisputed that IARC has never concluded that titanium dioxide in fact causes cancer
20 in humans—nor has any scientist or government authority. UMF No. 53; *see also* Norris Decl.,
21 Ex. J (“Jameson Dep.”) at 83:2-4 (“To the best of my knowledge I don’t know that anyone has
22 identified titanium dioxide as a known human carcinogen.”). OEHHA certainly has never made
23 that determination for itself. UMF No. 34. When IARC classified titanium dioxide as a Group 2B
24 possible human carcinogen, it explicitly acknowledged that there was “inadequate evidence in
25 humans,” meaning the available evidence did not show the presence of absence of a causal
26 association. UMF No. 4, 16. The only evidence that supported IARC’s classification consisted of
27 two animal bioassays—the Lee (1985) and Heinrich (1995) studies—involving rat inhalation.
28 UMF No. 20. But as the AG’s expert concedes, these rat studies were “not designed to show

1 concordance between tumor sites in animals and humans” (Jameson Dep. 100:10-12); nor were
2 they designed to be extrapolated to humans. *Id.* at 151:10-21.

3 It is undisputed that the Lee and Heinrich studies undergirding IARC’s classification of
4 titanium dioxide—which in turn supply the sole basis for titanium dioxide’s listing under
5 Proposition 65—exposed rats to lung overload, the mechanism by which titanium dioxide was
6 found to cause cancer in rats. UMF Nos. 21-22, 25. But as discussed, *supra* 2-3, the rat lung-
7 overload model has no relevance to cancer risk (or hazard) in humans. Dr. Jameson does not dispute
8 this; instead, he even acknowledges that particle clearance in rat lungs is different from other
9 species, including humans, and indeed there is no evidence that humans experience particle
10 overload from titanium dioxide exposure. Jameson Dep. 115:11-14; 138:12-30. Even the Lee
11 study’s authors cautioned that the human “biological relevance” of the rat tumors in their
12 experiment is “negligible.” UMF No. 54. The State’s expert, meanwhile, admits that the Heinrich
13 study was “poor[ly]” designed, in part because of the “low number of animals.” Jameson Dep.
14 188:3-5; *see also id.* at 179:14-21 (commenting that it is a “bad study”). Not surprisingly, both
15 studies have been widely discredited by other scientists and governmental bodies. UMF No. 22.

16 The epidemiological data fares even worse. In line with IARC’s determination that the
17 evidence of carcinogenicity in humans is “inadequate,” Dr. Boffetta concluded that the “available
18 evidence from human studies [] cannot be credibly relied on to conclude that exposure to TiO₂
19 causes *any* cancer.” Boffetta Decl. ¶ 100; UMF Nos. 62-86. The basis for this conclusion is laid
20 out in Dr. Boffetta’s nearly 30-page expert report, in which he critically assesses dozens of
21 epidemiological studies and meta-analyses published since 1988. Tellingly, the AG has presented
22 *no* expert evidence to refute Dr. Boffetta’s report. The State’s sole expert to opine on the scientific
23 evidence, Dr. Jameson, admits that the AG “did not ask [him] to comment on the Boffetta report,”
24 perhaps because he is not an epidemiologist. Jameson Dep. 67:10-19. Indeed, Dr. Jameson never
25 addresses the expert opinions of Dr. Boffetta. And when asked whether he reviewed Dr. Boffetta’s
26 report, he replied: “I skimmed through it. I really didn’t read it in any detail.” Jameson Dep. 61:4-
27 5. This admission undercuts any attempt by the AG to present a dispute of material fact as to the
28 evidence of Listed Titanium Dioxide’s carcinogenicity in humans.

1 Indeed, when presented with Dr. Boffetta’s central conclusion that the weight of
2 epidemiological evidence does not show a positive association between titanium dioxide and
3 cancer, the State’s own expert agreed. Jameson Dep. 70:24-71:10 (admitting that Dr. Boffetta’s
4 conclusion “makes sense”). Dr. Jameson further describes the epidemiology data assessed by
5 IARC as “very weak.” *Id.* at 56:25-57:1; *see also id.* 228:8-19 (explaining how the studies “suffered
6 from exposure misclassifications,” had “missing” data “which didn’t allow for good exposure
7 estimates,” and “were not of a sufficient duration”). Puzzlingly then, he criticizes Dr. Madl’s
8 conclusion by cherry-picking Dr. Boffetta’s 2004 study and mischaracterizing it as “strengthening
9 the classification of titanium dioxide as a possible human carcinogen.” ECF No. 42, Ex. 2, Jameson
10 Report at 14-16. Having neglected to carefully read Dr. Boffetta’s report, however, he fails to
11 acknowledge that Dr. Boffetta himself states (¶ 60) that “the results of this study do not support the
12 hypothesis that exposure to TiO₂ is a cause of lung or other cancers.”

13 In a nutshell, there is no credible support for the claim that exposure to Listed Titanium
14 Dioxide from using a cosmetic or personal care product increases a person’s risk of cancer. The
15 epidemiological data lends no evidence for a positive association between Listed Titanium Dioxide
16 and cancer of any form; to the contrary, Dr. Boffetta’s *unrefuted* expert report indicates that it *does*
17 *not* cause cancer in humans. UMF No. 55. The two rat inhalation studies that IARC deemed
18 sufficient for finding carcinogenicity in animals, while tenuous from the start, have been discredited
19 in the decades since their publication as unreliable indications for human cancer risk.

20 To borrow Chief Judge Mueller’s reasoning in the acrylamide case, a Proposition 65
21 warning here “implies misleadingly that the science about the risks of [Listed Titanium Dioxide] is
22 settled.” *CalChamber*, 529 F. Supp. 3d at 1121. This Court should reaffirm its findings on the
23 preliminary injunction motion that “the two Prop 65 warning requirements for Listed Titanium
24 Dioxide are not purely factual because they tend to mislead the average consumer” (ECF No. 40 at
25 16) and grant summary judgment in PCPC’s favor.

26 4. The Warning is Controversial Because of the Significant Scientific Debate.

27 With insufficient epidemiological data, the State can only prevail by showing that there is
28 a “strong scientific consensus” that rat tumors found in inhalation experiments where the rats were

1 subjected to lung overload imply human carcinogenicity. *See NAWG*, 85 F.4th at 1278. But no
2 such consensus exists. Indeed, the issue of whether studies showing particle-overload-related lung
3 tumors in rats can be extrapolated to humans, *i.e.*, whether these studies are relevant to humans, is
4 scientifically controversial, at best. This alone is “sufficient to place [the] Prop 65 warning outside
5 the realm of the lower level of review under *Zauderer*.” *Id.* at 1282.

6 On this issue, the undisputed factual record shows that there is nowhere near a consensus
7 among scientific experts. UMF No. 56. Dr. Madl characterized the ongoing scientific controversy
8 as revolving around the “relevance of particle-overload-related lung tumors in rats following
9 chronic inhalation exposures to poorly soluble low toxicity particles for human risk assessment.”
10 Madl Report ¶ 35 (describing the “considerable debate” over the issue). Even Dr. Jameson
11 acknowledged “hear[ing] that debate over and over again.” Jameson Dep. 117:4-20; *see id.* at
12 232:8-23 (noting “argu[ments] in a number of papers” that tumor formation in rats from lung
13 overload “is not relevant to the human situation because humans don’t have particle overload”).

14 For their part, government authorities who have reviewed them have found the two rat
15 studies on which the IARC classification is based to be unreliable as indicators that titanium dioxide
16 poses a cancer risk in humans. The European Chemicals Agency found one of the studies to be
17 unreliable and irrelevant for purposes of human cancer risk assessment. UMF No. 31. And the
18 European Court of Justice, after determining that the other study was also unreliable, went so far
19 as to *annul* a regulation that required labeling of titanium dioxide as carcinogenic by inhalation.
20 UMF No. 32. The FDA, meanwhile, has long accepted titanium dioxide as safe and appropriate for
21 use in cosmetics and other products, which only underscores the divided assessment. UMF No. 3.
22 California’s OEHHA, of course, has not evaluated either study and merely listed titanium dioxide
23 automatically based on the IARC classification. UMF Nos. 33-34.

24 On top of this “as-yet-unresolved scientific debate,” the warning requirement is also
25 controversial because PCPC’s members are “forced to convey a message fundamentally at odds
26 with their businesses.” *NAWG*, 85 F.4th at 1278. In this way, the compelled warning is both
27 objectively *and* subjectively controversial. The warning requirement as applied to Listed Titanium
28 Dioxide in cosmetics, therefore, is “undeniably controversial,” and fails the *Zauderer* test. *See id.*

1 **B. The Warning Requirement is “Unjustified [and] Unduly Burdensome.”**

2 Finally, the undisputed factual records shows that the compelled warning requirement as
3 applied to Listed Titanium Dioxide cannot satisfy *Zauderer*’s third element. *See NIFLA*, 585 U.S.
4 at 776 (“Even under *Zauderer*, a disclosure requirement cannot be ‘unjustified or unduly
5 burdensome.’”). The AG must prove that the compelled disclosures “remedy a harm that is
6 potentially real not purely hypothetical” and “extend no broader than reasonably necessary.” *Id.*
7 (internal quotations omitted). Otherwise, they are unjustified and must fail.

8 Proposition 65’s warning mandate for Listed Titanium Dioxide is unjustified because it
9 addresses a purely hypothetical harm. The State’s purported interest in Proposition 65’s required
10 warnings is in informing Californians about exposures to “chemicals that are scientifically
11 known—not merely suspected, but known—to cause cancer” in humans. *Lungren*, 14 Cal. 4th at
12 306-07. But as the factual record proves, whether exposure to Listed Titanium Dioxide causes or
13 even increases the risk of cancer in *humans* is far from settled science. *See supra* Part II.A.4. The
14 State cannot demonstrate that a cancer warning for Listed Titanium Dioxide informs consumers
15 about a chemical that is “scientifically known” to pose a risk of cancer in humans—at best, the AG
16 can only show that it causes lung tumors in rats under conditions of lung overload. Indeed, the very
17 authority that triggered the chemical’s listing on Proposition 65 concluded that there is “inadequate
18 evidence” of human carcinogenicity after determining that “studies do not suggest an association
19 between occupational exposure to titanium dioxide” and risk of cancer. UMF No. 5. In other
20 words, the alleged “harm” that California wants consumers to be warned of is not only
21 “hypothetical”—it is entirely unproven.

22 But “[e]ven if California had presented a nonhypothetical justification,” the warning
23 requirement here imposes an undue burden and fails independently on that basis. *NIFLA*, 585 U.S.
24 at 777. The Court need not linger on this point, for the Ninth Circuit’s decision in *CERT* is
25 dispositive. *See* 29 F.4th at 479-80 (citing “heavy litigation burden” as reason the compelled
26 warning for acrylamide was unduly burdensome). Here, even more so than in *CERT* (where
27 businesses had the benefit of a “No Significant Risk Level”), PCPC’s members whose products
28 contain Listed Titanium Dioxide are heavily burdened by Proposition 65 enforcement actions.

1 UMF No. 58. The AG cannot refute this. “[A] government-compelled disclosure that imposes an
2 undue burden” such as this “fails for that reason alone.” *ABA*, 916 F.3d at 757.

3 **C. The Warning Cannot Withstand Heightened Scrutiny.**

4 As this Court already acknowledged, if the State’s compelled disclosure “does not survive
5 *Zauderer*, it necessarily cannot survive *Central Hudson*’s more demanding test.” ECF No. 40 at
6 13 n.5; *accord ABA*, 916 F.3d at 756 n.5 (“Logically, [] if the warning does not meet [the] lower
7 standard” under *Zauderer*, “it necessarily does not meet [the] higher standard.”). Indeed, a cancer
8 warning requirement for Listed Titanium Dioxide in cosmetics cannot withstand heightened
9 scrutiny, even in its own right – for “California’s burden under this test is ‘heavy.’” *See Italian*
10 *Colors*, 878 F.3d at 1176 (citation omitted). To satisfy its burden under *Central Hudson*, the State
11 must show that the law “directly and materially advances a substantial government interest” and is
12 “no more extensive than necessary.” *Junior Sports Mags. Inc. v. Bonta*, 80 F.4th 1109, 1117 (9th
13 Cir. 2023). Said differently, California “must provide evidence establishing ‘that the harms it
14 recites are real,’” and that the law “will ‘*significantly*’ alleviate those harms.” *Id.*

15 California certainly has a substantial interest in public health, “[b]ut simply having a
16 substantial interest does not validate the state’s [compelled speech].” *Id.* By “compelling sellers
17 to warn consumers of a potential ‘risk’ never confirmed by any regulatory body—or of a hazard
18 not ‘known’ to more than a small subset of the scientific community—[California] does not directly
19 advance that interest.” *NAWG*, 85 F.4th at 1283; *see also Wheat Growers II*, 468 F. Supp. 3d at
20 1264 (“[M]isleading statements about [chemical]’s carcinogenicity . . . do not directly advance
21 [California’s] interest.”). As the undisputed factual record shows, Proposition 65 warnings in this
22 case are misleading, if not outright false. However viewed, compelling cancer warnings on
23 cosmetics for Listed Titanium Dioxide does not directly advance the State’s interest. *See id.*; *cf.*
24 *Video Software Dealers Ass’n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009) (“[T]he State
25 has no legitimate reason to force retailers to affix false information on their products.”).

26 On the contrary, enforcing the safe harbor regulations for “speculative, conjectural, or
27 tentative” risks “inevitably dilut[es] the force of any specific warning given.” *Dowhal*, 32 Cal. 4th
28 at 932-33. California jurists considering Proposition 65 have repeatedly explained that inundating

1 consumers with cancer warnings is counterproductive. *See, e.g., id.* at 932 (cautioning of the
2 “dangers of overwarning and of less meaningful warnings crowding out” those that are actually
3 “necessary”); *Env’t Health Advocs., Inc. v. Scream, Inc.*, 83 Cal. App. 5th 721, 733 (2022)
4 (explaining that Proposition 65’s purpose “would be stymied” by the “proliferation of unnecessary
5 warnings [that] distract the public from other important warnings on consumer products”).

6 The compelled cancer warning in this case also fails intermediate scrutiny for the
7 independent reason that California has “more narrowly tailored” options to inform the public about
8 cancer risks. *Italian Colors*, 878 F.3d at 1178 (availability of “numerous and obvious less-
9 burdensome alternatives” informs whether the compelled speech is narrowly drawn to achieving
10 the State’s interest). Less burdensome alternatives are legion. As the Ninth Circuit has observed
11 in upholding challenges to Proposition 65 warnings for other chemicals, “California could employ
12 various other means to promote its (minority) view that [the chemical] puts humans at risk of cancer
13 ‘without burdening [businesses] with unwanted speech.’” *NAWG*, 85 F.4th at 1283. For instance,
14 “the State could reasonably post information about [the chemical] on its own website” or pay for
15 advertising to convey its message. *Id.* It could also “fund scientific research and pursue public
16 awareness campaigns.” *CalChamber*, 529 F. Supp. 3d at 1121.

17 In the end, the State is free to “advance its own side of [the] debate” on the possible
18 carcinogenic effects of Listed Titanium Dioxide “through its own speech.” *Sorrell v. IMS Health*
19 *Inc.*, 564 U.S. 552, 578-80 (2011). But the “State’s failure to persuade” or refusal to explore these
20 options “does not allow it to hamstring” businesses by forcing them to disparage their own products
21 by parroting the State’s controversial and misleading message. *See id.* at 578. After all, “the First
22 Amendment does not permit the State to sacrifice speech for efficiency.” *Riley v. Nat’l Fed’n of*
23 *the Blind of N.C.*, 487 U.S. 781, 795 (1988).

24 **II. A PERMANENT INJUNCTION SHOULD ISSUE.**

25 A plaintiff seeking permanent injunctive relief must show “(1) that it has suffered an
26 irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to
27 compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and
28 defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved

1 by a permanent injunction.” *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006). The
2 standard of a permanent injunction is “essentially the same as for a preliminary injunction,” except
3 that the plaintiff must “show actual success, rather than a likelihood of success.” *Wheat Growers*
4 *II*, 468 F. Supp. 3d at 1265. In the time since this Court held that PCPC was entitled to a preliminary
5 injunction, the AG can point to no factual or legal development that would alter the Court’s correct
6 determination that the warning requirement as applied to Listed Titanium Dioxide was likely
7 unconstitutional. Therefore, a permanent injunction should issue.

8 “Irreparable harm is relatively easy to establish in a First Amendment case.” *CTIA II*, 928
9 F.3d at 851. Indeed, “[t]he loss of First Amendment freedoms, for even minimal periods of time,
10 unquestionably constitutes irreparable injury.” *Id.* (quoting *Elrod v. Burns*, 427 U.S. 347, 373
11 (1976)). And unlike monetary injuries, “constitutional violations cannot be adequately remedied
12 through damages.” *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1138 (9th Cir. 2009); *see also CERT*,
13 29 F.4th at 479 (recognizing that labeling products with Proposition 65 warnings damages a
14 business’s “reputation and goodwill”).

15 The final two factors—balance of equities and public interest—“merge when the
16 Government is the opposing party.” *Nken v. Holder*, 556 U.S. 418, 435 (2009). Both favor granting
17 a permanent injunction. The Ninth Circuit has “consistently recognized the significant public
18 interest in upholding First Amendment principles.” *Wheat Growers II*, 468 F. Supp. 3d at 1266
19 (quoting *Doe v. Harris*, 772 F.3d 563, 583 (9th Cir. 2014)). The State “has no legitimate interest
20 in enforcing an unconstitutional” law. *Id.* And, although California has an interest in accurately
21 informing its citizens of possible health risks, “[p]roviding misleading or false labels to consumers
22 also undermines [that] interest . . . at the expense of [PCPC’s] First Amendment rights.” *Id.*
23 Therefore, just as in *Wheat Growers II*, “the balance of equities and public interest weigh in favor
24 of permanently enjoining Proposition 65’s warning requirement” for Listed Titanium Dioxide in
25 cosmetics and personal care products. *See id., aff’d NAWG*, 85 F.4th at 1283; *see also CERT*, 29
26 F.4th at 481-82 (finding this Court had “sufficient reason to enjoin Prop. 65 acrylamide litigation”).

27 **III. DECLARATORY RELIEF IS APPROPRIATE.**

28 PCPC is entitled to a declaration pursuant to 28 U.S.C. § 2201 that the Proposition 65

1 warning requirement for cancer as applied to Listed Titanium Dioxide in cosmetic and personal
2 care products violates the First Amendment. The procedural requirements for such a declaration
3 are met: (1) “there is a case of actual controversy”; and (2) the Court should exercise its jurisdiction
4 to decide that controversy. *Am. States Ins. Co. v. Kearns*, 15 F.3d 142, 143-44 (9th Cir. 1994).

5 The first requirement is “identical” to establishing Article III standing. *Id.* at 143. The AG
6 has not challenged PCPC’s standing, and the undisputed factual record shows that many of PCPC’s
7 members have for years faced enforcement actions alleging they are required to provide warnings
8 for Listed Titanium Dioxide. UMF No. 58. For purposes of standing, “[i]t is well settled that
9 evidence of past instances of enforcement is important.” *LSO, Ltd. v. Stroh*, 205 F.3d 1146, 1155
10 (9th Cir. 2000). “[T]he Government’s failure to disavow application of the challenged
11 provision”—as here—is another factor in favor of finding standing. *Id.* And “when the threatened
12 enforcement effort[s] implicate[] First Amendment rights,” as they do here, “the inquiry tilts
13 dramatically toward a finding of standing.” *Id.* Absent a declaration from this Court, PCPC
14 members currently embroiled in the dozens of lawsuits alleging failure to warn of Listed Titanium
15 Dioxide and threatened with additional claims will continue to incur expenses and damages for
16 litigation, reformulation and testing, and/or unwarranted warnings. UMF No. [57].

17 As to the second requirement, declaratory relief is appropriate “(1) when the judgment will
18 serve a useful purpose in clarifying and settling the legal relations in issue, and (2) when it will
19 terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the
20 proceeding.” *Bilbrey by Bilbrey v. Brown*, 738 F.2d 1462, 1470 (9th Cir. 1984). Here, declaratory
21 relief would provide needed clarity as to the constitutionality of a misleading and controversial
22 warning requirement. It would “serve to delineate important [constitutional] rights” of PCPC’s
23 members who wish to lawfully do business. *See id.* at 1471. And it would put bounty hunters on
24 notice that they may no longer enforce this controversial application of Proposition 65.

25 CONCLUSION

26 For the reasons stated above, the Court should issue a permanent injunction against
27 enforcement of Proposition 65’s warning requirement as to Listed Titanium Dioxide in cosmetics
28 and personal care products, as well as a declaration that any such enforcement is unconstitutional.

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Respectfully submitted,

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